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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/816,173

04/01/2004

James F. Zucherman

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COATS & BENNETT/MEDTRONIC  
1400 CRESCENT GREEN  
SUITE 300  
CARY, NC 27518

EXAMINER

PHILOGENE, PEDRO

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

09/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/816,173	<b>Applicant(s)</b> ZUCHERMAN ET AL.	
	<b>Examiner</b> Pedro Philogene	<b>Art Unit</b> 3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 11, 21, 26, 36, 37, 40, 41, 62 and 66-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 21, 26, 36, 37, 40-41, 62, 66-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-8,11, 21,26, 36-37, 40-41,62,66-70,73,74, are rejected under 35 U.S.C. 102(b) as being anticipated by Howland et al. (5,496,318).

With respect to claim 1, Howland et al disclose a spinal implant comprising a spacer (10) having a longitudinal axis and first second end portions; the spacer (10) further having anterior edge and posterior edge and elongated therebetween in a first direction generally transverse to the longitudinal axis; as best seen in Fig.3; a first wing (16) disposed proximate the first end portion and disposed generally transverse to the longitudinal axis, the first wing elongated from a posterior edge to an anterior edge thereof in the first direction; as best seen in FIG.3, a distraction guide (15) disposed more proximate the second end portion than the first end portion and tapering away from the first wing (16) a second wing (20) disposed proximate the second end portion and the distraction guide, the second wing (20) disposed generally transverse to the longitudinal axis and removably mounted to at least one of the spacer and the distraction guide; the second wing elongated from a posterior edge to an anterior edge thereof in the first direction; as best seen in FIG.3. The second wing comprises a hole (21) therethrough, the first wing is continuous with the spacer, the distraction guide is continuous with the spacer; the spacer is rotatable about the longitudinal axis so as to

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variably position a narrower portion thereof relative to the first wing (if one so desired). Wherein, in cross-sectional view of the spacer normal to the longitudinal axis, a largest height of the posterior edge of the spacer taken perpendicular to a theoretical line extending between the anterior and posterior edges is greater than a corresponding largest height of the anterior edge of the spacer; as best seen in FIG.3; the spacer, when urged between the spinous of the adjacent cervical vertebrae, allows flexion but not extension and creates a contact surface with the bone of the spinous processes that increases as the wedge-like spacer moves anteriorly; as set forth in column 60-65; wherein the first wing and the second wing are angled outwardly (because of narrower second end) relative to each other to accommodate the anatomy of the adjacent spinous processes of the cervical spine.

With respect to the method claims, the steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 71- 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howland et al. (5,496,318) in view of Zucherman et al. (6,190,387).

It is noted that Howland et al did not teach of anterior and posterior edges of the spacer that are generally rounded; as claimed by applicant. However, in similar art,

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Zucherman et al provide the evidences of the use of a spacer having rounded anterior and posterior edges to increase the volume of the spinal canal and/or the neural foramen as the spacer is positioned between the spinous processes.

Therefore, given the teaching of Zucherman et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Howland et al; as taught by Zucherman et al to increase the volume of the spinal canal and/or the neural foramen as the spacer is positioned between the spinous processes.

### ***Response to Amendment***

Applicant's arguments with respect to claims 1-8,11-13,15,17-19,26,29,36-37,40-51,62-65 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/  
Primary Examiner, Art Unit 3733  
September 18, 2008

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